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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/646,748

12/11/2000

Julio Boza

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05/05/2006

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EXAMINER

MOHAMED, ABDEL A

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/646,748	Applicant(s) BOZA, JULIO	
	Examiner Abdel A. Mohamed	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

ACKNOWLEDGMENT TO REMARKS AND STATUS OF THE CLAIMS

1. The remarks filed 04/05/06 is acknowledged, entered and considered. Claims 1-16 are now pending in the application. The rejection under 35 U.S.C. 102(b) over the prior art of record has been considered but deemed to be moot in view of the new ground of rejection. Also, the Finality of the previous Office action is withdrawn in view of the following new grounds of rejections as set forth *infra*.

NEW GROUND OF REJECTIONS

CLAIMS REJECTION-35 U.S.C. § 102(b)

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by the product 100% Whey Protein 5 lbs, which is available in the market by Optimum Nutrition.

The instantly claimed invention as drafted in claims 1, 2 and 6 are broadly directed to methods for increasing glutamine by using whey protein having at least 80% by weight or a protein mixture in Markush format administered to a patient to increase plasma glutamine concentration in stressed mammal, i.e., the term “stressed mammal”

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is a non-limiting condition (claim 1), to increase muscle glutamine concentrations in mammal generally (claim 2), wherein the protein is hydrolyzed (claim 6). The product of Optimum Nutrition as evidenced on the cited web site search discloses the superior blend of whey protein isolates, concentrates and hydrolysates, wherein the whey protein isolates as the primary protein source contains 100% whey protein. The cited product is useful as a dietary supplement for the intended purposes of increasing plasma glutamine concentration in stressed mammal or for increasing muscle glutamine concentrations in a mammal. Therefore, the cited product discloses the invention substantially as claimed, in the absence of evidence to the contrary the nutritional formulation and its use thereof as disclosed by the product anticipate claims 1, 2 and 6 as drafted.

CLAIMS REJECTION-35 U.S.C. § 103(a)

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the product 100% Whey Protein 5 lbs, which is available in the market by Optimum Nutrition taken with Ballevre et al (U.S. Patent No. 5,849,335).

The product of Optimum Nutrition as evidenced on the cited web site search discloses the superior blend of whey protein isolates, concentrates and hydrolysates, wherein the whey protein isolates as the primary protein source contains 100% whey protein. The cited product (i.e., the primary reference) discloses a nutritional composition including a protein source having at least 81% by weight of a whey protein (i.e., with 23 grams of protein in just a one ounce serving). Further, the cited product (the primary reference) discloses a nutritional composition providing 110 Calories per serving, wherein total protein is 23 g, total fat is 1.5 g, and total carbohydrate is 3 g with typical amino acid profile per scoop is cysteine 440 mg, glutamine and precursors 3870 mg, histidine 400 mg, isoleucine 1520 mg, and leucine 2470 mg. The above nutritional composition is used as a dietary supplement.

Furthermore, the claims of the instantly claimed invention are broad because claims 1-16 are directed to methods for increasing glutamine by using whey protein or a protein mixture administered to a patient to increase plasma glutamine concentration in stressed mammal (claim 1), to increase muscle glutamine concentration in mammal (claim 2), to use as nutritional/therapeutic composition to a mammal suffering from injured, diseased or under-developed intestines (claim 3), wherein the mammal is a pre-term infant having an under-developed intestines (claim 4), wherein the protein is hydrolyzed (claims 5 and 6) and having the various molecular weights recited in claim 7,

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wherein the protein source provide energy of the nutritional composition thereof (claims 8, 11 and 14), wherein the nutritional composition further includes a lipid source (claims 9, 12 and 15) and wherein the nutritional composition includes carbohydrate source (claims 10, 13 and 16).

Although, the primary reference teaches the use of a nutritional composition comprising 100% whey protein for dietary supplement, however, the secondary reference of Ballevre et al ('335 patent) teaches a nutritional composition comprising a protein source including whey protein and a protein mixture having the amino acid profile of whey protein which is administered to stressed patients to increase the plasma glutamine concentration, or administered as nutritional support for increasing muscle glutamine concentration in athletes after exercise, or administered to patients suffering from injured or diseased intestines or to maintain the physiological functions of the intestines particularly in under-developed intestines (e.g., a pre-term infant or babies) as disclosed on the abstract; col. 1, lines 44-50; col. 3, lines 1-25; col. 6, lines 13-38; claims 24, 26-28 and 30. Thus, clearly meeting the limitations of claims 1-4.

On col. 4, the '335 patent discloses the use of nutritional composition wherein the whey protein is hydrolyzed whey protein, the protein source provides about 10% to about 30% of the energy of the nutritional composition, the nutritional composition further includes a lipid source which provides about 20% to about 40% of the energy of the nutritional composition and the lipid source comprises a mixture of medium chain and long chain fatty acids, and as such meet the limitations of claims 5, 6, 8, 9, 11, 12, 14 and 15. The secondary reference also discloses a nutritional composition which

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further includes a carbohydrate source which provide about 35% to about 60% of the energy of the nutritional composition and as such meet the limitations of claim 10, 13 and 16 (See e.g., col. 2, lines 46-64; col. 4, lines 4-56 and Examples 2-4).

Therefore, given the teachings of the product of primary reference of Optimum Nutrition which teaches the use of nutritional composition of 100% whey protein for dietary supplement, one of ordinary skill in the art would have been motivated at the time the invention was made to adapt the above scheme of the administration of nutritional composition, which contains whey protein (or a protein mixture which stimulates its acid profile) as a protein source for the same purposes (i.e., for increasing glutamine levels in plasma or muscle of a stressed patient, pre-term baby or athletes) of the secondary reference of '335 patent. Further, such features are known or suggested in the art, as seen in the secondary reference, and including such features into the composition/formulation of the primary reference would have been obvious to one of ordinary skill in the art to obtain the known and recognized functions and advantages thereof.

Therefore, the combined teachings of the cited references makes obvious the claimed invention because at the time the invention was made based on the combined teachings of the cited references and for the reasons given above, one of ordinary skill in the art would have easily adapt of using the already known process of the whey protein hydrolysate comprising glutamine for nutritional purposes (i.e., a metabolic process), which is a mechanism wherein the sum total of chemical and physical processes within the body related to release of energy by the breakdown of chemical

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fuel and the use of that energy by the cells for their own work. Thus, the combined teachings of the cited references clearly showing the known principles of physiology that naturally occurs after intake of food or meal that increases plasma glutamine concentration in mammals, increases muscle glutamine concentration in mammal and provides treatment to patients suffering from injured, diseased or under-developed intestines.

Accordingly, claims 1-16 are *prima facie* obvious over the combined teachings of the cited references, because it is an obvious modification of the cited references combined teachings for a nutritional composition including a protein source having at least 80% by weight of a component selected from either whey protein or a mixture which stimulates the amino acid profile of whey protein consisting of approximately 80% to about 90% by weight for nutritional purposes in the manner claimed, absent of sufficient objective factual evidence or unexpected results to the contrary.

CONCLUSION AND FUTURE CORRESPONDANCE

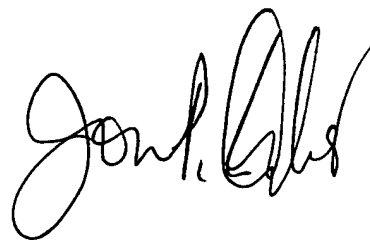
4. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CAMPELL BRUCE can be reached on (571) 272 0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jon Weber
Supervisory Patent Examiner

 Mohamed/AAM
April 27, 2006